

**HEADACHE- elaps corallinus, arsenicum alb., belladonna, bryonia, carduus benedictus, cimicifuga, coffea cruda, convallaria, crotalus horridus, digitalis, gelsemium, glonoinum, ignatia, lachesis, merc. viv., naja, nux vom., phosphorus, rhus toxicodendron, sanguinaria, secale, vipera berus, apis mel., hypericum, thuja occ.. pellet
Newton Laboratories, Inc.**

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Headache 2454P

INDICATIONS & USAGE SECTION

Formulated for associated symptoms such as throbbing pain, pressure, congestion, dizziness, nausea and light sensitivity.

DOSAGE & ADMINISTRATION SECTION

Directions: Ages 12 and up, take 6 pellets by mouth (ages 0 to 11, give 3 pellets) as needed or as directed by a health professional. Under age 2, crush/dissolve pellets in purified water. Sensitive persons begin with 1 pellet and gradually increase to full dose.

OTC - PURPOSE SECTION

Formulated for associated symptoms such as throbbing pain, pressure, congestion, dizziness, nausea and light sensitivity.

OTC - ACTIVE INGREDIENT SECTION

Equal parts of Apis mel. 6x, Hypericum 6x, Thuja occ. 6x, Arsenicum alb.15x, Belladonna 15x, Bryonia 15x, Carduus ben. 15x, Cimicifuga 15x, Coffea cruda 15x, Convallaria 15x, Crotalus hor. 15x, Digitalis 15x, Gelsemium 15x, Glonoinum 15x, Ignatia 15x, Lachesis 15x, Merc. viv. 15x, Naja 15x, Nux vom. 15x, Phos. 15x, Rhus tox. 15x, Sanguinaria 15x, Secale 15x, Vipera 15x, Elaps 30x.

INACTIVE INGREDIENT SECTION

Inactive Ingredients: Gluten-free, non-GMO, beet-derived sucrose (lactose-free) pellets.

QUESTIONS SECTION

newtonlabs.net - Questions? 800.448.7256

Newton Laboratories, Inc. FDA Est # 1051203 Conyers, GA 30013

OTC - PREGNANCY OR BREAST FEEDING SECTION

If **pregnant or breast-feeding**, ask a doctor before use.

WARNINGS SECTION

WARNINGS: Keep out of reach of children. Do not use if tamper-evident seal is broken or missing. If symptoms worsen or persist for more than a few days, consult a doctor. If **pregnant or breast-**

feeding, ask a doctor before use.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

Keep out of reach of children

PACKAGE LABEL

HEADACHE			
elaps corallinus, arsenicum alb., belladonna, bryonia, carduus benedictus, cimicifuga, coffea cruda, convallaria, crotalus horridus, digitalis, gelsemium, glonoinum, ignatia, lachesis, merc. viv., naja, nux vom., phosphorus, rhus toxicodendron, sanguinaria, secale, vipera berus, apis mel., hypericum, thuja occ.. pellet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55714-2454
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MICRURUS CORALLINUS VENOM (UNII: V0S6H36980) (MICRURUS CORALLINUS VENOM - UNII:V0S6H36980)	MICRURUS CORALLINUS VENOM	30 [hp_X] in 1 g	
ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC CATION (3+) - UNII:C96613F5AV)	ARSENIC TRIOXIDE	15 [hp_X] in 1 g	
ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA - UNII:WQZ3G9PF0H)	ATROPA BELLADONNA	15 [hp_X] in 1 g	
BRYONIA ALBA ROOT (UNII: T7J046YI2B) (BRYONIA ALBA ROOT - UNII:T7J046YI2B)	BRYONIA ALBA ROOT	15 [hp_X] in 1 g	
CENTAUREA BENEDICTA (UNII: 615Z10070E) (CENTAUREA BENEDICTA		15 [hp_X]	

CENTAUREA BENEDICTA (UNII: 6L5ZL09795) (CENTAUREA BENEDICTA - UNII:6L5ZL09795)	CENTAUREA BENEDICTA	15 [hp_X] in 1 g
BLACK COHOSH (UNII: K73E24S6X9) (BLACK COHOSH - UNII:K73E24S6X9)	BLACK COHOSH	15 [hp_X] in 1 g
ARABICA COFFEE BEAN (UNII: 3SW678MX72) (ARABICA COFFEE BEAN - UNII:3SW678MX72)	ARABICA COFFEE BEAN	15 [hp_X] in 1 g
CONVALLARIA MAJALIS (UNII: QHH4HVF5QE) (CONVALLARIA MAJALIS - UNII:QHH4HVF5QE)	CONVALLARIA MAJALIS	15 [hp_X] in 1 g
CROTALUS HORRIDUS HORRIDUS VENOM (UNII: YHA2XLJ956) (CROTALUS HORRIDUS HORRIDUS VENOM - UNII:YHA2XLJ956)	CROTALUS HORRIDUS HORRIDUS VENOM	15 [hp_X] in 1 g
DIGITALIS (UNII: FIT8QT9U8B) (DIGITALIS - UNII:FIT8QT9U8B)	DIGITALIS	15 [hp_X] in 1 g
GELSEMIUM SEMPERVIRENS ROOT (UNII: 639KR60Q1Q) (GELSEMIUM SEMPERVIRENS ROOT - UNII:639KR60Q1Q)	GELSEMIUM SEMPERVIRENS ROOT	15 [hp_X] in 1 g
NITRO GLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	15 [hp_X] in 1 g
STRYCHNOS IGNATII SEED (UNII: 1NM3M2487K) (STRYCHNOS IGNATII SEED - UNII:1NM3M2487K)	STRYCHNOS IGNATII SEED	15 [hp_X] in 1 g
LACHESIS MUTA VENOM (UNII: VSW71SS07I) (LACHESIS MUTA VENOM - UNII:VSW71SS07I)	LACHESIS MUTA VENOM	15 [hp_X] in 1 g
MERCURY (UNII: FXS1BY2PGL) (MERCURY - UNII:FXS1BY2PGL)	MERCURY	15 [hp_X] in 1 g
NAJA NAJA VENOM (UNII: ZZ4AG7L7VM) (NAJA NAJA VENOM - UNII:ZZ4AG7L7VM)	NAJA NAJA VENOM	15 [hp_X] in 1 g
STRYCHNOS NUX-VOMICA SEED (UNII: 269XH13919) (STRYCHNOS NUX-VOMICA SEED - UNII:269XH13919)	STRYCHNOS NUX-VOMICA SEED	15 [hp_X] in 1 g
PHOSPHORUS (UNII: 27YLU75U4W) (PHOSPHORUS - UNII:27YLU75U4W)	PHOSPHORUS	15 [hp_X] in 1 g
TOXICODENDRON PUBESCENS LEAF (UNII: 6IO182RP7A) (TOXICODENDRON PUBESCENS LEAF - UNII:6IO182RP7A)	TOXICODENDRON PUBESCENS LEAF	15 [hp_X] in 1 g
SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA CANADENSIS ROOT - UNII:N9288CD508)	SANGUINARIA CANADENSIS ROOT	15 [hp_X] in 1 g
CLAVICEPS PURPUREA SCLEROTIUM (UNII: 01G9XEA93N) (CLAVICEPS PURPUREA SCLEROTIUM - UNII:01G9XEA93N)	CLAVICEPS PURPUREA SCLEROTIUM	15 [hp_X] in 1 g
VIPERA BERUS VENOM (UNII: 0ORO6NCA4M) (VIPERA BERUS VENOM - UNII:0ORO6NCA4M)	VIPERA BERUS VENOM	15 [hp_X] in 1 g
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	6 [hp_X] in 1 g
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	6 [hp_X] in 1 g
THUJA OCCIDENTALIS LEAFY TWIG (UNII: 1NT28V9397) (THUJA OCCIDENTALIS LEAFY TWIG - UNII:1NT28V9397)	THUJA OCCIDENTALIS LEAFY TWIG	6 [hp_X] in 1 g

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55714-2454-1	28 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	01/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		01/31/2019	

Labeler - Newton Laboratories, Inc. (788793610)

Registrant - Newton Laboratories, Inc. (788793610)

Establishment

Name	Address	ID/FEI	Business Operations
Newton Laboratories, Inc.		788793610	manufacture(55714-2454)

Revised: 11/2020

Newton Laboratories, Inc.